

Tenneco Packaging  
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Lake Forest, Illinois 60045

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6693 19 OCT -7 1999 **Packaging**

September 17, 1999

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket Nos **98N-1230; 96P-0418; 97P-0197; and 99N-1307:**  
Comments of **Tenneco Packaging, Inc.**, Lake Forest, Illinois, on FDA announcements of July 6, 1999 regarding Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution; and Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels.

To the FDA:

**Background**

This letter contains the comments of **Tenneco Packaging, Inc.**, 1900 West Field Court, Lake Forest, Illinois ("Tenneco Packaging"), on the labeling aspects only of the FDA announcements of July 6, 1999 entitled Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution, 64 FR 36492, and Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels. 64 FR 36517. Tenneco Packaging submits two copies of these comments.

In summary, Tenneco Packaging believes that food safety is the most important public policy concern and has actively participated in expanding the application of Safe Handling messages on egg cartons. We support the egg industry's position outlined in comments submitted to FDA by the United Egg Producers (UEP) and Foodservice & Packaging Institute, Inc. (FPI), as it relates to the warning message. Additionally, for the reasons detailed below, Tenneco Packaging urges FDA to implement a one (1) year effectiveness date after publication of the final rule.

**Tenneco Packaging, Inc.**

Tenneco Packaging is a leading, market-driven packaging company, specializing in the communication and promotion, protection and transportation, and food merchandising and storage of products. It has 163 facilities in 18 countries, and employs 24,000 people. Annual revenues are approximately \$4.3 billion.

97P-0197

C743

Tenneco Packaging's egg cartons

Tenneco Packaging manufactures and sells over a billion egg cartons annually, all manufactured from 100% Reclaimed Paper. These cartons are custom printed for hundreds of individual egg producers, some of which are large, but most of which are quite small. All our customers, regardless of size, rely on us to provide printed cartons that comply with all applicable legal requirements, including labeling requirements, and require us to advise them on the content of those requirements.

Over 75 % of the egg cartons sold by Tenneco Packaging are "Vue Style", most of which have just over 21 sq. inches of printing space. Vue Style cartons conform to the shape of the eggs and have segments cut out to allow consumers to view the eggs inside without lifting the lid. As FDA is aware, this type of carton facilitates swifter, safer cooling of eggs. FDA has recognized that "the way eggs are packaged" affects the internal temperature of eggs, and, in turn, the ability of *Salmonella* Enteritidis to grow and reproduce. 64 FR 36499.

At least 40% of Tenneco Packaging's cartons already have safe handling label statements

We support all reasonable efforts to improve food safety, and support in concept the agency's efforts to better inform consumers about safe handling of shell eggs. Indeed, over 450 million (approximately 40 percent) of the cartons sold by Tenneco Packaging currently feature a safe handling message. Most of those messages, pursuant to the recommendation of the American Egg Board, read as follows, enclosed within a hairline box:

**SAFE HANDLING INSTRUCTIONS**

- Always keep eggs refrigerated.
- Wash hands before and after handling.
- Cook thoroughly. Do not consume raw.
- Keep hot foods hot and cold foods cold.

Alternate wording appears on the remaining cartons that feature safe handling statements. Most of those with alternate wording feature the following label within a hairline box:

**Keep Food Safe**

- CLEAN Wash hands and surfaces often.
- SEPARATE Don't cross-contaminate.
- CHILL Refrigerate promptly.
- COOK Cook to proper temperatures.

**Tenneco Packaging Opposes the Proposed 180-Day Effectiveness Date**

Tenneco Packaging opposes the proposed effectiveness date of any final rule of 180 days after publication. This time frame is not long enough to make the necessary label changes, and is too short to assure that all or nearly all preprinted carton stock will be able to be used before the effectiveness date, minimizing both waste and economic loss.

**Label changes are impractical in 180 days**

A 180-day effectiveness date is not sufficient when the time required for new label design, approval from customers and production are considered. On the date the final rule appears, the 180 days begin to run, and new label designs for the hundreds of Tenneco Packaging customers will need to be developed. Then, these new designs will need to be sent to the customers for label approval, which, based on our past experience, can conservatively be expected to take 60-90 days. Production of the newly designed labels could not begin until that approval is obtained.

Further, once that production begins, it will involve label changes for thousands individual stock-keeping units ("SKU's") of hundreds of different customers, a burdensome undertaking under any circumstances, especially so given the 90 days or less of time expected to remain before effectiveness begins.

After careful examination of all the necessary activities involved with the expected redesign, and specific enumeration of the estimated time needed for each, we have developed a thorough estimate of the time needed for the label changes. Based on this detailed analysis, Tenneco Packaging personnel are expected to have to devote an estimated 11,386 to 19,880 hours to undertake a full redesign and then retooling of all carton labels, including artwork, communications with customers, plate ordering, and other activities.

It is not likely, moreover, that all or even most egg producers will have begun using the safe handling statement "that complies with" the proposed rule by the date of publication of the final rule, so that they might take advantage of the agency's offer to allow stock depletion of any such cartons printed with the statement called for in the proposed rule. 64 FR 36510. To do so would involve having to risk bearing the costs of two label changes within a period of time in which only one change would be legally required. Moreover, as noted, many of these same egg producers are even today addressing the safety issue by providing a safe handling statement on their cartons. They are unlikely to see the value of changing to FDA's proposed specified language now, knowing that within a year or two they very well might need to change again.

*Stock must be prepared well in advance*

The impracticality of a 180-day effectiveness date is also reflected in two realities of the egg carton business of Tenneco Packaging. First, Tenneco Packaging services hundreds of individual customers by custom-printing cartons, and must often prepare stock well in advance of its use date. The vast majority of customers Tenneco Packaging serves are smaller customers that use less than 30 million cartons per year. This means if a customer's needs for cartons are lower than the projections upon which the production level was based, Tenneco Packaging or the egg producers will be required to discard printed cartons that are not utilized prior to the new effective date.

Second, the egg carton business is highly cyclical, with the heaviest sales periods for eggs -- and hence, egg cartons -- coming at the Christmas and Easter seasons. The demand for egg cartons during those seasons is so high, and so much higher than at all other times of year, that Tenneco Packaging is unable to meet its customers' demands through ordinary production schedules.

If consistent production is not maintained, Tenneco Packaging risks running out of the cartons needed by its customers, which ultimately will result in shortages to consumers. Tenneco Packaging builds up enormous levels of inventory, primarily the small volume designs for the many small producers among its customers, with no guarantee that the producer will need the inventory at the predicted pace. Because we have equalized production throughout the year, this build-up necessarily occurs during what would otherwise be the slower production months from April (after Easter) through December.

Under ordinary circumstances, a downturn in demand merely results in use of the inventory over a longer period of time than originally predicted. However, if a rule change becomes effective within this time frame, and pre-printed cartons become illegal, discard of inventory is unavoidable.

Such discards place a financial burden on egg producers, many of them small businesses, because their contractual obligations to Tenneco Packaging call for them to pay for all cartons produced, even if in excess of their actual need. The cost of discards and new printing will fall on them, and could be passed on to the consumer.

**Tenneco Packaging proposes a 1-year effectiveness date**

For all the reasons detailed above, Tenneco Packaging proposes that the labeling requirements become effective one (1) year after publication of the final rule.

**A longer compliance period does not significantly reduce or delay the intended benefits of the rule, because benefits are already being realized**

We recognize that FDA has attempted to be sensitive to these issues in formulating its proposal, in part based on information provided by the egg and egg carton industries. FDA notes in the preamble, "The main disadvantage of longer compliance periods for the labeling provision . . . is that the option would delay the realization of the benefits of the rule." 64 FR 36507.

However, this does not take into account the fact that so many cartons already feature safe handling statements to the same effect as those in the proposed rule. Therefore, the benefits of the rule are already being largely realized in the case of all those cartons that are already labeled.

**FDA recognizes a 1-year effectiveness will reduce costs**

FDA recognizes that a 1-year effectiveness date will result in lower costs to industry, using two different means of calculation.

\*Table 13a in the Preliminary Regulatory Impact Analysis, 64 FR 36530, estimates total redesign costs for pulp paper cartons to be \$7,500,000 for 12-month (1 year) effectiveness period, versus \$10,000,000 for a 6 month (180 day) period.

\*Table 14 in the Preliminary Regulatory Impact Analysis, 64 FR 36531, estimates that total industry costs from implementation of this rule will be \$12,000,000 using a 12-month (1 year) effectiveness period, as compared with \$18,000,000 for a 6 month (180-day) period.

Inasmuch as the agency's justification for all aspects of this proposal is required to be a balancing of costs and benefits, it should reconsider the wisdom of the 180-day period in light of these salient facts about how the industry works.

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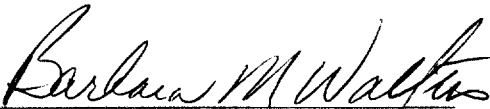
**If a 180-day effectiveness date is maintained, the final rule should publish in March**

If a 180-day effectiveness date is utilized, Tenneco Packaging respectfully requests that FDA publish the rule in March of the year it appears, with effectiveness to begin in September. This will allow the new designs to be created and approved during the time period in which the build-up for inventory typically takes place, thereby minimizing the effects of the inventory fluctuations described above on the egg industry and ultimately, on the consumers.

Thank you for your consideration. We would be happy to provide any additional information FDA might need.

Respectfully submitted,

TENNECO PACKAGING, INC.

By 

Barbara M. Walters  
Vice President

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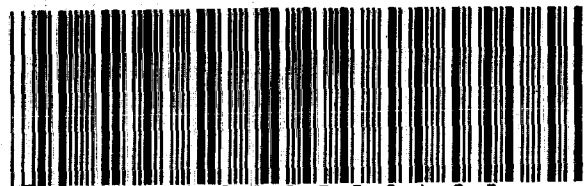
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